



Newsletter - Vol 13, No 1, March 2011 ● International Society of Oncology Pharmacy Practitioners

### President's Message

Spring is in the air (at least here in Belgium) and this is the symbol for more light, longer days, new life, more activity.

It seems that ISOPP is following that rhythm very closely as a lot of things are happening right now.

First of all we had the elections for secretary and 2 secretariat (= board) members. We had a full slot of candidates so the membership had a choice. The results showed a close match between the candidates. Elected as new secretary is Hannelore Kreckel from Germany and the 2 new boards members are Robert Terkola from Austria and Felicity Wright from Australia. Congratulations and welcome as officers of ISOPP. A great "thank you" for the people ending their term serving ISOPP on May 1°, Judith Smith as secretary, Harbans Dhillon and Ruth Tramshek as board members. Your contribution, input and cooperation was much appreciated by me and the other board members and I am sure this does not mean an end of your activities within ISOPP.

For the other ISOPP members who were not elected, thank-you for running and know that next year there is another opportunity, as we are going into yearly elections. In 2012, the positions of treasurer, president elect and 2 general secretariat members will become vacant.

As we want to encourage pharmacy assistants to become members as they make a valuable contribution, and it has been noted that there was no difference between the membership

fees for pharmacy assistants and pharmacists, the secretariat decided to install a new category of ISOPP members; pharmacy assistants. The membership fee decided for them is 50 % of the country band, a simple letter from the head of the pharmacy where they are working submitted together with the application form is the only extra documentation which is required. As you can seen on the website, two Requests For Proposals (RFP's) are out now, 1 for management services and 1 for hosting the congress in 2014. The purpose of the management RFP is to improve and facilitate our organisational capacity and skills, this is done more in the background of the society's functioning and the only thing you as a member will note is smoother and quicker communications besides an easier ( electronic) way of payment and application forms.

For the congress of 2014, as an ISOPP member there is a role you can play. You can as an individual or a group of colleagues compete for the organization of the ISOPP 2014 congress. All details can be found on the website. As we are a global organization, we move around the world with our congresses. If we follow the rotation pattern, North America/ Canada would be the usual place for the 2014 congress BUT it is not a necessity. I can guarantee you that all submissions will pass the scoring process and will be discussed on an equal bases, and who knows ..... I cannot stress enough the importance of the website for you and for us. All the announcements ( election candidates,



results, RFP, etc...); the highlights of oncology/hematology literature; the new on-line education cases, the audit tool for the standards of safe practice, the membership discussion forum and more are waiting for you to be explored. It is the hard work of many committee members to prepare these items, using them is the appreciation and validation of their work.

Kind regards and happy Easter to you all,

Johan

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#### **Congratulations to the new Secretariat members**

Congratulations to the NEW Secretariat who were elected in the ISOPP first ever electronic elections. The following individuals take their office officially May I, 2011. Please offer your congratulations to them Secretary - Hannelore Kreckel Secretariate Members

- Robert Terkola
- Felicity Wright go to the ISOPP website (Secretariat News section) www.isopp.org Carole Chambers, ISOPP Returning Officer



Secretary: Hannelore Kreckel, Germany



Secretariat member: Robert Terkola, Austria



Secretariat member: Felicity Wright, Australia

#### Call for proposal to host ISOPP in 2014

Many of you are looking forward to our next ISOPP Symposium in Melbourne, Australia in May of 2012. Our Bi-Annual Symposium is one of the premier educational events for Oncology Pharmacists from all parts of the world to participate in. It's a time to learn, visit with colleagues from all over the world, and make new friendships/connections.

One of the traditions at the close of each Symposium is the much anticipated announcement of the venue for the next Symposium. We have been fortunate to have Symposia all over the world; and have adopted a quasi rotation of 'North America', 'Europe', 'Rest of the World' to make travel to Symposia most economical for the majority of our membership.

We are now putting out the call for proposals to host the 2014 ISOPP symposium. With last year's Symposium being held in Prague, and the next Symposium in Australia; the Symposium rotation would call for a host location in North America; however this does not exclude submissions for a location outside of North America!! All submissions will be evaluated equally regardless of location, according to established criteria and budget. The criteria/checklist for evaluating submission is posted on the ISOPP website with this call. Please look at and address these criteria, budget requirements in your submission.

The deadline for submissions is: June 1, 2011

All submissions will be scored by the Secretariat and Committee Chairs from which a 'short list' of 2-3 venues will be selected. More in-depth review of criteria and budgeting will be done with host organizing committees into September; and a final venue will be selected by the end of September 2011

Submissions are to be submitted to:

John Wiernikowski, BScPhm, PharmD, FISOPP John.wiernikowski@gmail.com

#### **Australasian ISOPP meeting 2011**

The Australasian ISOPP meeting will be held in Melbourne on the 13th August.2011. This one day meeting will be a mixture of presentations from medical oncologists and other specialists and experienced oncology pharmacists. For the first time, this meeting will be held back-to-back with a Society of Hospital Pharmacist's of Australia intermediate seminar in haematology/oncology pharmacy practice (11and 12th August). The full programmes for both meetings will be available shortly on the ISOPP website.

For any further information contact jillian.davis@austin.org.au This is an opportunity to visit Melbourne before the ISOPP XIII, May 9-11, 2012 symposium.



### **ISOPP XIII**

The Thirteenth International Symposium on Oncology Pharmacy Practice

MAY 9th - 11th 2012 • MELBOURNE, AUSTRALIA

#### **Oncology Pharmacy in Greece**

I have worked at "St Savvas" hospital in Athens, Greece since 1988.

St. Savvas anticancer hospital was set up before the Second World War and was the first oncology hospital in the country.

Today it has 400 beds, personnel of 1200, two oncology clinics, one haematology clinic, and a variety of surgery clinics, three radiotherapy clinics and a 50 bed Day Clinic that treats about 80 patients per day. These are supported by the Radiology Department, the Pathology and Laboratory Medicine Departments and the Genetics Department. There is also a Medical Research Institute that we are very proud of.

The pharmacy department employs three pharmacists, three pharmacy assistants, one nurse for the transport of reconstituted drugs to the clinics, two secretaries and two couriers for transport of drugs and medicinal material to the clinics

The Pharmacy Department services include:

- Purchase of medicines and medicinal material from pharmaceutical companies
- Registration of invoices and charge of insurance companies
- Dispensing of medicines and medicinal material to the clinics.
- Preparation of cytotoxic drugs in a central unit.
- Communication and collaboration with the medical personnel and administration staff.
- Participation in hospital committees (drug committee, oncology committee, hospital infections committee)

Each pharmacist trains two pharmacy students. The law dictates for each student the period of training lasts for three months.

The pharmacy department services are on line and connected to the central electronic information system of the hospital.

Because of a predetermined budget the



Ioanna Saratsiotou, Head of the Pharmacy Department

orders of medicines are electronically approved by the hospital manager. Then the order for each supplier is printed separately and sent by fax. In one or two days we receive the medicines. After we count them, we register the invoice into the electronic system. For budget reasons we order medicines in such a way that we have only a 15 day stock. Therefore ordering is a daily occupation and responsibility of the head of the pharmacy department.

The electronic control and approval of every prescription for each and every patient of the hospital is also a responsibility of the pharmacists. If the dosage and or the indication are not correct, the prescription is not dispensed and the pharmacist notifies the doctor. Only the pharmacist can dispense narcotics drugs.

I must point out that the pharmacy department is involved in the fiscal management of drug therapy. Especially nowadays the participation of the head of pharmacy department in the drug committee is very critical.

In addition the pharmacy department is in charge of drug dispensing to cancer patients on an out-patient basis, a very time consuming endeavour. For example in our hospital we dispense drugs for supporting therapy and oral chemotherapy at home to approximately 400 patients per month. Patients from private hospitals or medical centres can also obtain their supporting therapy or oral chemotherapy from our pharmacy department. All the prescriptions are registered into the computer and charged to the insurance companies. The patients are informed about the dosage, the proper storage and dispensing of their prescribed drugs. Their most frequently asked question is whether the doctor has prescribed a "good drug". Our answer to them is that there is neither a "good" nor a "bad" drug but rather the proper drug for each disease and each patient's condition.

I would like to briefly review the history of our cytotoxic drug reconstitution service.

In 1991 the administration of our Hospital decided that the pharmacy department should be responsible for the reconstitution of cytotoxic drugs and a central preparation unit was set up.

That decision was based on the increase in the number of cancer patients, the desire to limit hospital personnel exposure to cytotoxic drugs and mainly the need to offer qualified treatment to the patients.

We encountered several obstacles in

the beginning:

Our lack of experience.

The lack of relevant expertise in Greece. the including right procedures for drug reconstitution. error avoidance and accident prevention.

Our efforts were also hindered by the lack of necessary specialized equipment. Since we



John and Persa, pharmacy assistants

#### **Oncology Pharmacy in Greece continued**

were the only central cytotoxic drug preparation unit in the country, there was no commercial interest for the import of such devices by the pharmaceutical companies.

Another major challenge was to convince the hospital personnel to participate.

At that time one pharmacist was reconstituting the drugs and one nurse was distributing them to the clinics, in ready to use form (infusion bag).

In 1991 we were preparing 12 therapies per day, 5 days a week.

In 2004 a One Day Clinic with the capacity to treat 50 patients daily was set up in the hospital.

Today we prepare 80 therapies daily, 5 days a week and 25 therapies on Saturdays. Currently the pharmacy department staff involved in the central preparation unit consists of 1 pharmacist, 2 pharmacy assistants, and 1 nurse, during the weekdays

and of 1 pharmacist and 1 pharmacy assistant on Saturdays.

In our daily routine we follow the European Standards of Quapos.

All involved personnel use protective equipment. Toxic waste handling follows the national guidelines. In addition the staff have regular medical check-ups and are entitled to an additional

10 days of vacation time per year compared to other hospital personnel. It's a bonus for who want to take part to our lab.

In conclusion, I would like to stress that my team and I personally are especially proud because during the last 10 years we have managed to improve the running of the department, and we are still trying to make things even better.



Stelios (pharmacy assistant) mixing chemotherapy.

**loanna Saratsiotou** PharmD Head of the Pharmacy Department "St Savvas Anti-cancer Hospital of Athens".

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#### A Path to Follow

Hungary is a small country at the transition between Central and Eastern Europe with a population of less than 10 million.

Currently there are 12 centers throughout the country where patients can get oncological treatment, and the only specialized hospital is the National Institute of Oncology located in the capital, Budapest. Oncology care providers are not equally eligible to prescribe medications for outpatients, making the Institute of Oncology, the highest level of cancer care a very busy place. Parts of the institute are being refurbished with the help of a European Union project, serving as a great opportunity to review sections of the clinical services provided there and elsewhere, for possible "renovation".

A national goal was set to achieve a 10% decrease in the cancer mortality rate in 10 years within the framework of the National Anti-Cancer Programme

announced in 2005. It is of course not enough to improve facilities and services; healthcare professionals need to be continuously educated and join lifelong learning standards.

Hospital pharmacists in Hungary are still not involved in clinical services. Local exceptions occur but the presence of

a clinical pharmaceutical service is based solely on personal values and knowledge and varies in presentation. A Youth Committee was founded this year by a group of young hospital pharmacists as part of the Hospital Pharmacy Section of the Hungarian Society of Pharmaceutical Sciences. Our primary aim is to reform roles of pharmacists in oncology centers, as a large-scale consequence of which we hope to improve quality of health care.

My personal belief is that we can learn a lot from other professionals; therefore I decided to dedicate some time to visit pharmacists around the world, and observe "how they do it".

I was surprised by the kind welcome and the willingness to show me around in every institute I went to. The pharmacists I met had a great impact



Azienda Ospedaliera Sant' Andrea, Rome, Italy

on the way of my thinking and my knowledge.

The first places I visited in 2010 were two hospitals in Rome, Italy: Azienda Ospedaliera Sant' Andrea, and Instituto Nazionale Tumori Regina Elena, where I met Dr. Felice Musicco, and I was shown how pharmacovigilance should be run, and which tasks should be carried out. In Tokyo, Japan I received a warm welcome from Professors Shinichiro Okamoto and Yusuke Tanigawara and staff of the pharmacy unit of Keio University Hospital. I learned that clinical pharmaceutical services were routinely implemented into their daily activities, and they provided cancer patients with fantastic, printed material regarding therapy. Outpatients were thoroughly counselled on their oral medications too. The Royal Marsden Hospital in London, UK represents the heights of oncology pharmacy service to me. I received a warm welcome and a complete, tailored schedule from Helen Moulsdale by the help of which I could see the whole range of clinical pharmacy activities. I met specialised pharmacists (sarcoma specialist. breast cancer specialist, GI specialist, etc.), took part in patient consultations, saw their guidelines, their proformas, and a system that appeared flawless to me.

According to the experiences I gained in other countries so far, I must admit that we lack fundamental tools in our practice, and therefore a few initial steps must be determined: we must have

Keio University Hospital, Tokyo, Japan

guidelines (or SOPs) not only for a few proceedings, for everything that routinely done in the hospital; our computer system needs more be "user friendly" and accessible all pharmacists; proformas

need to be reconsidered and pharmacists should check each chemotherapy prescription and most importantly, pharmacists should be entrusted with clinical responsibilities. I recognised the second step as the setting up of a medicines information service.

The object we proposed to ourselves within the Youth Committee is to complete the initial steps by the means of trials that can demonstrate significant advantage of our interference, in the field of oncology. Three centers have been chosen, three hospitals, and pivotal trials have been launched in one of them, the aim of which is to gauge the frequency and grade (CTCAE v4.0) of certain adverse drug reactions (tyrosine kinase inhibitor related rash, hand-foot syndrome, extravasation, phlebitis, hand-foot skin reaction, mucositis) related to cancer treatment, and measure the efficacy and benefits of prevention. Protocols

> have been written by us, and the local ethical committee in one center has already accepted them.

> Probably the best way to success is to learn from those who have brought something to proficiency. There are certain trends in the world of pharmacy today that will determine the future of health care of every country. We want to learn and join the stream of progression to provide better



Instituto Nazionale Tumori Regina Elena, Rome, Italy

health care for Hungarian cancer patients too. There is a long road ahead of us, but with the guidance provided to us by friendly colleagues from different parts of the world, aims we set can be achieved.

#### Alexandra Bartal

National Institute of Oncology Budapest, Hungary

# **ISOPP XIII**



The Thirteenth
International
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Pharmacy Practice

MAY 9<sup>th</sup> -11<sup>th</sup> 2012 MELBOURNE, AUSTRALIA

### 33rd Annual San Antonio Breast Cancer Symposium

(SABCS)

The 33rd Annual San Antonio Breast Cancer Symposium (SABCS), presented in collaboration with the Cancer Therapy & Research Center (CTRC) and the American Association for Cancer Research (AACR), took place December 8-12, 2010 in San Antonio, Texas. This year nearly 8,000 attendees from more than 90 countries attended the meeting.

The scientific program consisted of various lectures and mini-symposia by experts in both clinical and basic research, poster presentations, and oral slide presentations. Over 1,000 abstracts were accepted representing medical, surgical, and radiation oncology. Approximately 50 abstracts were selected for oral presentation during the general sessions.

Of the many interesting presentations, below are selected highlights from the general sessions which includes: 3 studies investigating combination targeted therapy for HER2+ early stage breast cancer; 2 studies addressing the role of CYP2D6 testing for predicting efficacy of adjuvant tamoxifen, and the results of the AZURE trial investigating the use of adjuvant zoledronic acid in early stage breast cancer.



**Press Conference** 

Photo Courtesy © SABCS/Todd Buchanan

### Combination targeted therapy for HER2+ early stage breast cancer

Results of 3 trials investigating the role of trastuzumab, pertuzumab (an antibody that binds to HER2 at a site independent of trastuzumab), and lapatinib in the neoadjuvant setting for early stage HER2+ breast cancer were presented. The **GeparQuinto study** was a phase III, randomized study comparing the effects of lapatinib vs. trastuzumab on pathologic complete response (pCR) rates when given in combination with anthracycline-taxane neoadjuvant based chemotherapy (EC followed by docetaxel). The trastuzumab containing demonstrated

significantly higher pCR rate which was 31.3% with EC-docetaxel+trastuzumab vs. 21.7% with EC-docetaxel+lapatinib. **NEOSPHERE** trial was randomized phase II study evaluating 4 neoadjuvant treatment arms on pCR rates: docetaxel + trastuzumab, docetaxel + trastuzumab + pertuzumab, pertuzumab, trastuzumab + docetaxel + pertuzumab. The pCR rate was greatest in the docetaxel, trastuzumab, and pertuzumab arm (45.8%). **NeoALTTO** was a phase III, randomized, open-label trial that tested the efficacy of lapatinib, trastuzumab, or their combination when given with paclitaxel as neoadjuvant therapy. The pCR rate was significantly greater in the combination lapatinib + trastuzumab arm (51.3%) compared to either single agent. Adverse effects from these trials were consistent with known toxicity profiles, and consisted predominantly of increased diarrhea seen in the lapatinib regimens. Results of these studies demonstrate that dual HER2 blockade increases pCR rates and suggests that targeted HER2 therapies used in combination may provide greater anti-tumor efficacy. However, all of these trials report only on pCR rates, and we do not have disease free survival (DFS) or overall survival (OS) results yet, which will help clarify if this strategy leads to long-term benefits.

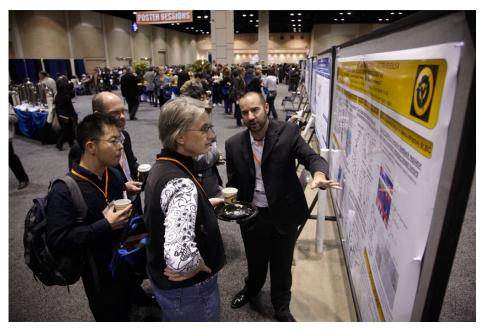


Photo Courtesy © SABCS/Todd Buchanan

Given the high cost of these drugs, discussion surrounding the economic implications of this strategy was also addressed.

## CYP2D6 testing and efficacy of adjuvant tamoxifen

CYP2D6 enzyme is involved in the biotransformation of tamoxifen to its active metabolite, endoxifen. Individual genetic polymorphisms of CYP2D6 may result in patients being poor (PM), intermediate (IM), or extensive (EM) metabolizers. Several studies in the literature have reported conflicting results regarding the role of CYP2D6 genetic variation as a predictive marker to tamoxifen efficacy. Two new studies on the topic were presented at the meeting. These were 2 separate retrospective analyses investigating outcomes according to CYP2D6 status, based on patients from the 2 large, prospective adjuvant tamoxifen ATAC and BIG 1-98 trials. Both studies concluded that CYP2D6 genotypes and phenotypes were not associated with tamoxifen clinical outcomes and that there is insufficient evidence to recommend testing. However, there are limitations to these studies in that they are retrospective, there is lack of standardization of definitions, and lack of control for drugs interactions. Since there also other enzymes involved endoxifen pharmacokinetics prospective studies may be needed. However, clinical implications were discussed and it was mentioned that routine testing was not justified to determine whether to give tamoxifen, but that women should still be informed



Photo Courtesy © SABCS/Todd Buchanan



Photo Courtesy © SABCS/Todd Buchanan

of the controversy surrounding tamoxifen pharmacogenetics.

### Adjuvant zoledronic acid: Results from the AZURE trial

Evidence (including the ABCSG-12 trial) suggests there may be a benefit to using adjuvant zoledronic acid for antitumor effects in early stage breast cancer. The AZURE trial investigated whether adjuvant zoledronic acid reduces recurrence in patients with high risk early stage disease. This was a phase III trial which randomized 3,360 patients with stage II/III breast cancer to standard therapy +/- zoledronic acid to complete 5 years of treatment. There was no significant difference between treatment arms for both the primary endpoint of DFS and the secondary endpoint of OS. Adverse events were equivalent across study arms except for confirmed cases of osteonecrosis of the jaw, which occurred in the

> zoledronic acid arm but was not observed in the control arm. Discussion occurred as to why these results are in contrast to previous studies, and authors hypothesize that adjuvant bisphosphonate efficacy may dependent on a low

estrogen bone environment. This study does not support routine use of adjuvant bisphosphonates for antitumor effects in early breast cancer. Additional studies will provide more information.

Additional information on these studies and all abstracts are available at www. sabcs.org.

Janet Espirito, PharmD, BCOP Clinical Coordinator, Pharmacy Practice US Oncology The Woodlands, Texas



Paul Goss, MD, PhD, MBBCH,
Photo Courtesy © SABCS/Todd Buchanan

### **ASBMT and CIBMTR Meetings**

The Tandem Meetings of the ASBMT and CIBMTR were held once again from the 17th to 21st of February in Hawaii. Aside from the obvious advantages of traveling to Hawaii, the program was up to the usual excellent standard. I attended with my friend and colleague Tracy Shields, a paediatric BMT pharmacist. We were glad we attended together because we could divide and conquer when it was difficult to decide which concurrent session to attend. As a BMT pharmacist attendance at the 2 day BMT pharmacist meeting is extremely valuable but understandably the paediatric BMT day was a big draw card for Tracy. We both got a lot out of the sessions for BMT advanced practitioners too (registrars and nurse practitioners).

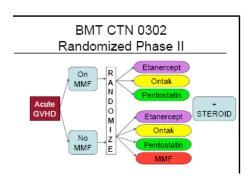
Progress in cancer treatment is often in small incremental steps, which add up over time to substantial improvements. Such improvements depend on a lot of hard research work in big multicentre trials. Some of the big questions in haematopoetic stem cell transplant (HSCT) are difficult to answer in this way because most centres are small so recruitment of adequate patient numbers depends on co-operation between a large number of centres to set trials up and manage patient care consistently. Questions like how to manage steroid refractory GVHD (graft versus host disease) or which conditioning protocols provide the best compromise between disease control and long term toxicity. The BMT clinical trials network (CTN) was set up to facilitate the big studies needed. The answers will be sometime in coming and many more questions will be raised along the way. However, one study which has already concluded is BMT CTN 0302, a phase II study of 4 different treatments in steroid refractory GVHD patients.

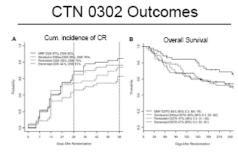
Mycophenolate was the winner and that should interest transplant pharmacists. Mycophenolate exposure has been shown to correlate with outcome in other transplant modalities. Inadequate

levels in the first week after HSCT have been associated with increased risk of engraftment failure and GVHD. However, mycophenolate bioavailability is lower than normal in HSCT patients and quite variable. Controversy exists around the most clinically relevant measure of mycophenolate exposure. Should we measure mycophenolic acid? Should we measure the active metabolite as well? What is the best limited sampling strategy to measure the AUC? If mycophenolate fulfils it's promise in steroid refractory GVHD in the phase 3 BMT CTN study, I am sure BMT pharmacists will need to assist their physician colleagues closely to best utilise this pharmacokinetically challenging drug.

One of the most interesting (and challenging) things about HSCT is that even relatively innocuous drugs can requirecareful consideration. Dr. George MacDonald is a gastroenterologist at the Fred Hutchinson Cancer Centre in Seattle and he spoke to us about his work on hepatotoxicty of HSCT conditioning. He showed that the high risk of sinusoidal obstruction syndrome associated with BuCy conditioning is not due to busulphan alone. In fact, busulphan metabolism depletes glutathione stores, and in glutathione depleted patients, cyclophosphamide metabolism pushed towards is the more hepatotoxic CEPM

metabolite. Paracetamol (aminocetaphen) metabolism also depletes glutathione stores. As a result it is general practice avoid paracetamol during busulphan administration and clearance. However, by the same token paracetamol should also be avoided during administration and clearance of high cyclophosphamide dose which is not as widely appreciated. Given that thiotepa is also partially





Alousi, A. M. et al. Blood 2008:114:511-61

cleared via glutathione dependant hepatic metabolism and melphalan is known to be more hepatotoxic when given after busulphan in BuMel than on it's own Dr. MacDonald also advocates avoidance of paracetamol during melphalan and thiotepa. Therefore, the biggest practice change I have taken from my attendance at this meeting is to avoid paracetamol conditioning chemotherapy with busulphan, cyclophosphamide and thiotepa and with melphalan when given after Busulphan.

Diana Booth Melbourne, Australia



Diana and Tracy enjoying some free time in Hawaii